

Notice of Allowability

Application No.

10/049,381

Examiner

Janet L. Coppins

Applicant(s)

DELFOURNE ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Amendment of July 19, 2005.
2. ☒ The allowed claim(s) is/are 1-5 and 7-16, newly renumbered 1-5, 11, 6-10, and 12-15.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Claims 1-5 and 7-16 are pending in the instant application.

Response to Amendment

1. Receipt is acknowledged of Applicants' Amendment, filed July 19, 2005, which has been reviewed by the Examiner and entered of record in the file. Accordingly, claim 12 has been amended, and new claims 15-16 have been added.

Claim Rejections - 35 USC § 112

2. Claim 12 previously rejected under 35 U.S.C. 112, first paragraph, as not being enabled. Pursuant to the interview of March 9, 2005, and the recommendations made in the previous Office Action of April 19, 2005, Applicants have limited the scope of claim 12 in order to encompass certain cancers that are fully enabled by the specification. Therefore the enablement rejection has been obviated and the Examiner withdraws the rejection to the claims.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. S. Maurice Valla, on October 3, 2005.

The application has been amended as follows:

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A) Claim 12, line 5, please add the following language at the end of the claim (after “astrocytomas”), “comprising administering an effective amount of a compound as defined in claim 1 to said patient.”

B) Claim 15, line 5, please add the following language at the end of the claim (after “astrocytomas”), “comprising administering an effective amount of a compound as defined in claim 1 to said patient.”

REASONS FOR ALLOWANCE

4. In view of Applicant’s amendatory changes, claims 1-5 and 7-16, newly renumbered as claims 1-5, 11, 6-10, and 12-15, are allowable over the prior art. The following is an examiner’s statement of reasons for allowance:

This invention relates to novel pentacyclic aromatic alkaloids (phenanthrolin-9-one compounds) and their pharmaceutical compositions that have cytotoxic activity and are useful as anti-tumor agents. The allowable claims in this case are 1-5 and 7-16, and are directed to compounds, compositions, methods of preparation, and methods of use. Phenanthroline compounds such as ascididemin are known in the art as having cytotoxic activity. However the aspect of preparing the instant claimed phenanthrolin-9-one pharmaceutical compositions according to formulae I and Ia are neither anticipated nor fairly suggested by the prior art. After a thorough search, the closest of prior art, Bracher et al, was found to teach similar pentacyclic alkaloid compounds isolated from marine organisms known as ascididemins. However Applicants have differentiated from Bracher et al by deleting hydrogen and –OAc from the definition of R₃, in addition, Bracher et al fail to disclose pharmaceutical compositions containing said compounds, and do not teach methods of use. Therefore, the prior art fails to

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teach, anticipate, or fairly suggest the instant claimed phenanthroline-9-one compounds, compositions, processes of preparation, or methods of use.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699699. The fax phone number for the organization where this application or proceeding is assigned is 571.272.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
September 28, 2005

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Kamal Saeed
Joseph K. McKane
SPE, Art Unit 1626